Section 5 - 510(k) Summary

APR 18 2011

K110136

Prepared: 11 January 2011

510(k) Owner Trudell Medical International
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CANADA

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Device Name

Proprietary ***RespiChamber**** Valved Holding Chamber
Common Holding Chamber, Direct Patient Interface

Product Code NVP

Classification Regulation 868.5630

Predicate Device

510(k) #	Trade/Model Name	Manufacturer
K962822	OptiChamber Advantage Valved Holding Chamber	Respironics New Jersey, Inc.

Device Description

The ***RespiChamber**** Valved Holding Chamber (VHC) is a device used for the administration of metered dose inhaler medication to a spontaneously breathing patient. By means of a one-way valve, medication particles are held in the chamber for several seconds after actuation has occurred enabling inhalation by the patient. The device is designed to minimize delivery of the larger particles of aerosolized medication, which may otherwise lodge in the mouth, throat and upper airway, while allowing the smaller therapeutic particles to be inspired.

Intended Use

The ***RespiChamber**** Valved Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed

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by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.

Technological Characteristic Comparison to Predicate Device

Both the ***RespiChamber**** VHC and the predicate device utilize a reservoir and one-way valve system through which metered dose inhaler medication passes to the patient. While the operating principle is similar, the design of each of the systems is unique. Non-clinical testing of the ***RespiChamber**** VHC and the predicate device demonstrate the differences in product design lead to no new issues of safety or effectiveness.

Non-Clinical Test Summary

Evaluation of the ***RespiChamber**** VHC and the predicate device was performed in accordance with the relevant sections of the CDRH Guidance Document *"Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH/ODE/DCRD/ADDB -1993).*
Particle size distribution testing has been conducted with three drug classification types. The determination of the mass of each drug emitted in the therapeutic range (Fine Particle Mass, μg < 4.7 μm) demonstrates that the performance of the ***RespiChamber**** VHC raises no new issues of safety or effectiveness from the legally marketed predicate device.

Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The ***RespiChamber**** VHC has been evaluated against a currently marketed (predicate) device for the determination of substantial equivalency. The ***RespiChamber**** VHC and the predicate device share common indications for use, usage environments, and method of operation. The devices are both single patient use, non-sterile, disposable and are available by prescription.

Performance data, gathered in accordance with *"Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH/ODE/DCRD/ADDB -1993)*, demonstrate that the ***RespiChamber**** VHC raises no new issues of safety or effectiveness from the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Darryl Fischer
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APR 18 2011

Re: K110136
Trade/Device Name: RespiChamber Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Holding Chambers, Direct Patient Interface
Regulatory Class: II
Product Code: NVP
Dated: January 17, 2011
Received: January 18, 2011

Dear Mr. Fischer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110136

Device Name: RespiChamber Valved Holding Chamber

Indications for Use:

The RespiChamber Valved Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.

Prescription Use: ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K110136